## Hearing Loss Signals Need for Diagnosis

training to hear? Do people say you're talking loudly? Thinking about ordering a hearing aid or sound amplifier from a magazine or late-night TV advertiser?

Doing so could delay the diagnosis of a treatable or serious ear condition and lead to further hearing loss or other complications.

"The problem might be as simple as a wax impaction blocking the ear canal, which is easily treated, or at the other end of the spectrum, it could be something as serious as a tumor pressing on the hearing nerve," says Eric Mann, M.D., Ph.D., clinical deputy director for the Division of Ophthalmic, and Ear, Nose, and Throat Devices at the Food and Drug Administration (FDA).

Many cases of hearing loss are related to aging and exposure to loud noises, and a hearing aid, or frequently one for each ear, might be the solution. But while a prescription is not required for most kinds of hearing aids, it's important to see a health care professional not only to rule out other medical causes of hearing loss, but to ensure that hearing aids are properly fitted and come with follow-up care.

"Sometimes there are issues with comfort. Perhaps you can't wear a particular hearing aid because it is



scratching the ear canal," said Mann. "There are sometimes problems with a whistling noise from the hearing aid known as 'feedback' because it's not a proper fit in the ear canal. These are all issues a hearing health care professional will work through with you."

## **Aids Versus Amplifiers**

Mann adds that consumers should not confuse hearing aids with the personal sound amplification products (PSAPs.) Although some PSAP technology is similar to that of a hearing aid, only hearing aids are intended to make up for impaired hearing.

A PSAP, in contrast, is for people with normal hearing who have a desire or need to amplify sounds in certain situations. For example, a PSAP may be helpful for hunters or bird-watchers. They are often advertised as a way to listen to a television set to a low volume that won't disturb someone sleeping nearby.

FDA regulates hearing aids as medi-

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cal devices in order to assure their safety and effectiveness. PSAPs are not subject to medical device regulations, although they are subject to other safety regulations as an electronic product that emits sound vibrations. FDA recently issued a draft update to this guidance to clarify what claims are appropriate for each of these two distinct types of products.

Differences among hearing aids themselves are more complex, which is one of the reasons a professional should be involved. Because hearing loss affects people in different ways, you need a device appropriate for your condition, and tailored to your lifestyle. A librarian, for example, might need different features in a hearing aid than a concert manager or a salesperson who spends the workday on the phone.

Hearing aids of various sizes may be worn behind the ear, in the ear or completely in the ear canal. Some include directional microphones, which allows sound coming from a specific direction to be amplified to a greater degree than sound from another direction. Some have switches specifically for telephone conversations, or inputs to allow you to plug directly into an electrical device, such as a TV or computer.

## **Buyer Beware**

FDA strongly encourages a medical evaluation before the purchase of a hearing aid. Hearing aid sellers are required to tell you about the importance of a medical evaluation before they sell the aid. If you decide to forego an evaluation, you must sign a waiver.

Your primary care doctor may refer you to a specialist in ear, nose and throat conditions—an otolaryngologist (commonly known as an ENT specialist)—for evaluation and diagnosis of hearing loss. Two types of hearing health professionals that are authorized to measure hearing loss and dispense hearing aids include:

Audiologists, who must have at least a master's degree and specialized training in hearing loss.

Hearing aid dispensers, who are licensed by states under varied requirements.

The Federal Trade Commission advises consumers to avoid businesses that dismiss the need for a medical exam before selling you a hearing aid. Other advice includes:

- Seek a licensed hearing aid professional who offers products from several manufacturers.
- Ask whether there is a trial period—most states require 30-60

day trial periods.

- Find out what exactly is refundable if you return the hearing aid during the trial period.
- Examine the details of the warranty, including whether you'll get a free loaner if your device needs serving and repair.
- Check whether the price quoted includes testing and follow-up services.

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